Remarks/Arguments:

This is a reply to the office action of June 30, 2004.

The examiner has raised two formal objections against claim 24, which in our opinion appear to be justified. First, we have changed "tatric" to –tartaric–. The examiner was also correct in objecting to the term "mixtures thereof" in claim 24. Indeed, the present application is directed to the use of one single fruit acid. We have therefore deleted the term "mixtures thereof" from claim 24.

The rejection of the claims of this application over prior art is traversed. The examiner is requested to reconsider the rejections in view of the following arguments.

The main line of argumentation of the examiner is based on Demopoulos (EP-A-0 444 000) . The examiner asserted that Demopoulos teaches an effervescent preparation comprising glucosamine sulphate and therefore anticipates the subject matter of the present application. We respectfully disagree.

We submit herewith a declaration of Andrea Wiesmann, an employee of Swiss Caps AG. In the declaration, Dr. Wiesmann explains why Demopoulos does not teach an effervescent preparation of glucosamine sulphate. Most importantly, Dr. Wiesmann conducted an experiment with the composition of example 1 of Demopoulos and verified that this is not an effervescent preparation. As described in item 7 of the declaration, upon addition of the composition of Demopoulos to water, only a very slight generation of carbon dioxide could be observed. The reason is that, on one hand, the acid used is not acidic enough in order to generate carbon dioxide from the applied carbonate, and on the other hand, calcium carbonate has a too low solubility in water. It is well known that solid components react much slower than dissolved components. Ascorbic acid, which is the acid source used by Demopoulos, is not capable of

reacting in a sufficient amount with calcium carbonate, especially not in the ratio of the components used by Demopoulos

In summary, the composition of Demopoulos generates only a very small amount of carbon dioxide when dissolved in water. This is of course in complete contrast to the requirements for an effervescent preparation. An effervescent preparation must dissolve completely and very quickly in water by generating carbon dioxide. A patient would not wait several hours for his medicine to be dissolved completely. As convincingly demonstrated by Dr. Wiesmann's declaration, Demopoulos does not teach an effervescent preparation.

The subject matter claimed in the present application is therefore not anticipated by Demopoulos, since the claims recite an effervescent preparation comprising glucosamine sulphate. As a consequence, the rejections of the examiner under 35 USC 103 are believed to be moot. None of the references cited by the examiner teaches or suggests an effervescent preparation of glucosamine sulphate. Thus, none of the prior art references provides a solution to he problem of providing a storage-stable formulation of glucosamine sulphate which contains a sufficiently large amount of the active ingredient for once-a-day dosage. According to the present application, this problem is solved by providing an effervescent formulation. On one hand, an effervescent formulation provides all the advantages of a solid formulation such as a tablet, including storage stability. On the other hand, by providing an effervescent preparation, the solid formulation, e.g. in tablet form, can be increased in size since the patient does not have to swallow the tablet as it is. Rather, the tablet is dissolved by generation of carbon dioxide and can therefore be taken in liquid form. This is not rendered obvious by the cited art.

In this respect, it is noted that while Demopoulos suggested incorporating higher amounts of glucosamine sulphate into its formulation, he completely failed to teach

how this could be done. As also outlined in the declaration of Dr. Wiesmann under item 8, the teaching of Demopoulos is clearly limited to oral dosage forms such as tablets and capsules. The only example in Demopoulos is related to the preparation of a capsule comprising around 400 mg glucosamine sulphate. This is in accordance with the preferred range for glucosamine sulphate indicated by Demopoulos at col. 6, lines 40 to 42. It is not possible to administer amounts of up to 1500 mg glucosamine sulphate in a tablet or a capsule intended to be swallowed, since such tablets or capsules would simply become too large.

In summary, we believe that the subject matter of the present claims is neither anticipated nor rendered obvious by the cited references.

Respectfully submitted,

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September 30, 2004